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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,227	11/10/2000	Ewing B. Gourley	16790-6411	4736

21888 7590 03/10/2005
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EXAMINER

PORTER, RACHEL L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Requirement for Information Under 37 C.F.R. § 1.105

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.
2. The information is required to identify products and/or services embodying the disclosed subject matter for processing pharmaceutical orders to determine appropriate (i.e. "own use") discounts. The Examiner, upon conducting a review of the prior art submitted in the IDS received 8/24/2001, noted an undated pamphlet from Health Resources USA, L.L.C, the assignee of the instant application. The document describes a consortium among pharmacies and nursing homes, and also describes a "closed distributor" pharmaceutical system. The pamphlet further describes a system that audits pharmaceutical orders, and limits transactions strictly to "own use" qualifying pharmacies.

In response to this requirement please provide the date that the submitted pamphlet was published/generated. Also, please provide any other known publications, brochures, manuals and press releases that describe the Health Resources USA, LLC as described by the aforementioned document, and specifically what products or services were marketed or developed before 11/10/2000, that was the subject of the pamphlet disclosure.

3. The fee and certification requirements of 37 C.F.R. § 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those

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documents within the scope of this requirement under 37 C.F.R. § 1.105 that are included in the applicant's first complete communication responding to this requirement.

Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 C.F.R. § 1.105 are subject to the fee and certification requirements of 37 C.F.R. § 1.97.

4. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

5. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained will be accepted as a complete response to the requirement for that item.

6. This requirement is subject to the provisions of 37 C.F.R. §§ 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).**

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is 703-305-0108. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703)305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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ALEXANDER KALINOWSKI
PRIMARY EXAMINER

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RESOURCES
USA, L.L.C.**

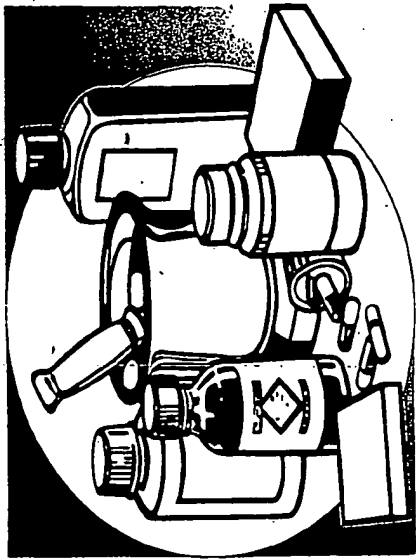
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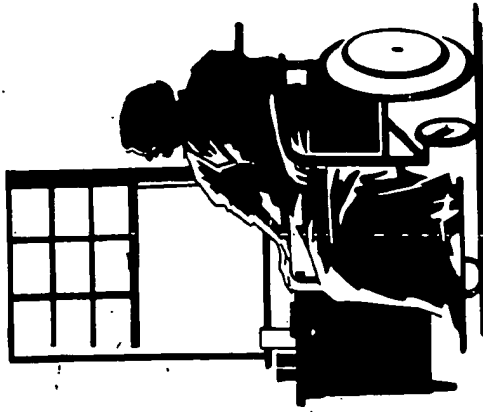
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**HEALTH
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- **A DIRECT CUSTOMER SALES
MARKETING ENTERPRISE**
- **CONSORTIUM BUILDING
WITH LONG TERM CARE
DISPENSERS**
- **BUNDLING PRODUCTS FOR
DISPENSING AND
DISCOUNT PRICING**
- **CONTROL AND
ACCOUNTABILITY**

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A DIRECT CUSTOMER SALES MARKETING ENTERPRISE

BACKGROUND: In 1998 there were 17,039 nursing homes in the United States representing a service capacity in excess of 1.8 million beds. Discounts for prescription drugs that are dispensed to nursing home residents and, therefore, meet the definition of "own use" as defined in *Abbott Laboratories, et al. vs. Portland Retail Drugists Assn., Inc.*, 425 U.S. 1, 96 S. Ct. 1976) are available from manufacturers. Presently these discounts are received by approximately sixty percent (60%) of the nation's nursing homes. Nursing homes usually do not have pharmacies located on the premises and contract for pharmacy services separate from the nursing facility. The contracted pharmacies comprise both closed and retail pharmacies. The facilities served by closed pharmacy contracts have been afforded discounts via their contract agents, the closed pharmacies. The balance of nursing homes (the forty percent (40%)) served by retail pharmacies contracted within the community have been unable to obtain "own use" discounts. A large number of these retail pharmacies are pharmacist owned and operated with the pharmacist serving as the nursing home pharmaceutical consultant. This community vested professional is identified as part of the nursing home staff and is personally in the facility on a regular schedule. The pharmacy consultant is a member of the facility's "quality assurance" committee and meets regularly with the other members of the committee, which include the facility physician, psychiatrist and nursing staff. He knows his customer/patients personally, reviews their prescriptions every month and files a report with the nursing home containing his recommendations for changes. In marketing terms, the "elasticity" of this relationship is obvious.

THE MARKET: Historically, pharmaceutical manufacturers have observed and reaped the benefits of the product demand (elasticity) that is generated by acute and long-term care providers with their captive clientele. Because every manufacturer of brand name prescription drugs has some degree of market power, each can charge different prices dependent on the elasticity of demand from different classes of purchasers (that is, the responsiveness of quantity demanded or rejected by a change in price). They find the least elastic purchasers are retail pharmacies, because they must stock a full range of drugs in order to be able to fill prescriptions of walk-in-customers. In contrast, a nursing home has a more elastic demand because it can influence the physician's choice of which brand name or generic to prescribe and thus assure a volume of product if the price is right. In the case of retail pharmacies that contract with nursing homes, this elasticity (which leads to brand and price sensitivity and market power dynamics) has been untapped by the manufacturers. This market is at least 6,816 facilities with a bed complement of 733,928 beds. At a national average of 87% occupancy this translates to 638,517 people, every single one of them prescription drug users.

CONSORTIUM BUILDING WITH LONG TERM CARE DISPENSERS

The retail pharmacy business is inelastic and is not generally the focus of a manufacturer's market power. However, forty percent (40%) of the nation's nursing homes constitute an important sub-class within the retail pharmacy business and unlike the walk-in-customer, the nursing home has collective clout with the physicians who actually order prescription drugs. The retail pharmacy dispensing to a nursing home is really involved in two different businesses. It still serves the walk-in-customer but the known quantity of nursing home residents that they serve constitutes a "direct customer sales" base with elastic demand. It is our mission to identify these special pharmacies and serve the nursing home dispensing part of their businesses by identifying the specific product demand that is or can be generated by this "own use" customer — the nursing home.

BUNDLING PRODUCTS FOR DIS- PENSING AND DISCOUNT PRICING

Discount pricing of pharmaceuticals has been available to pharmacies that serve only institutional customers, and no others, for almost three quarters of a century. Retail pharmacies that serve institutional customers have been excluded, until now, from any price discounts for their nursing home accounts. The principals of Health Resources USA, LLC, have the necessary systems, procedures, and experience to measure the elasticity of this untapped market and the safeguards to prevent product diversion. Since the retail pharmacist and the nursing home must dispense and administer medications via a controlled protocol, Health Resources will utilize a unique application of this protocol to identify and bring selected products from manufacturer to nursing home at "own use" discount prices.

CONTROL AND ACCOUNTABILITY

Drug manufacturers have struggled with the dilemma of profiting from utilizing "own use" captives while avoiding the diminution of their efforts by attempting to control the diversion of specially discounted product to the general market. The entities that the manufacturers have historically relied on for product distribution, the general wholesalers, seem to be the least equipped to handle the special pricing that must necessarily be made to the "own use" customer. In July, 1999, a federal grand jury indicted two Kansas City pharmacists, their employees, and a wholesaler on charges they conspired to sell pharmaceutical wholesalers more than \$10 million in prescription drugs they had fraudulently purchased at a discount. Health Resources' unique, patent-pending process is focused on the supply of "own use" pharmaceuticals to nursing homes under "direct customer" and "plant delivery" agreements with manufacturers. Health Resources is a "closed distributor" with a single mission. Health Resources will maintain a patient-related data bank that will generate orders and provide for inventory control. Proof of "own use", customer-direct data is updated monthly and can be audited by any supplying manufacturer. Health Resources "closed distribution" system strictly precludes the ordering or shipping of any general wholesale or retail product and consequently restricts its transactions, exclusively, to "own use" qualifying pharmacies.